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ఆంధ్రప్రదేశ్ రాజపత్రము

THE ANDHRA PRADESH GAZETTE

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PART I EXTRAORDINARY

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NOTIFICATIONS BY GOVERNMENT

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AGRICULTURE & COOPERATION DEPARTMENT
(Agri.III)

ESTABLISHMENT OF MANUFACTURING UNITS WITH FAKE AND BOGUS ADDRESSES, SELLING OF BIO-PRODUCTS MIXED WITH CHEMICALS-SYSTEM IMPROVEMENT - REGULATION MECHANISM PROPOSED - CONVENED OF TECHNICAL HIGH LEVEL COMMITTEE MEETINGS - GUIDELINES/ REGULATIONS FINALIZED.

[G.O.Ms.No.18, Agriculture & Cooperation (Agri.III), 10th March, 2017.]

NOTIFICATION

BIOPRODUCTS - DEFINITION :

Bio-Product means, any substance / product / preparation / formulation prepared from natural sources of Biological origin intended for use in agriculture either through soil application or foliar application, for the improvement of Crop or Crop produce and which are for time being not covered under any of the laws of the Insecticides Act, 1968 and Fertiliser (Control) Order 1985.

PROTOCOLS TO BE FOLLOWED BY MANUFACTURES / MARKETERS OF BIOPRODUCTS FOR MARKETING OF BIO-PRODUCTS IN ANDHRA PRADESH STATE:

1) Compulsory Enumeration with Department of Agriculture
2) After Enumeration with department of Agriculture, the quality control team conducts inspection with regard to existence of the unit and availability of minimum infrastructural / analytical facilities required (Annexure-I) for manufacture of bio-products.
3) The bio-product manufacturers should follow minimum protocols for establishing manufacturing unit as mentioned in Annexure II.
4) The quality control team to furnish report within 30 days from the date of Enumeration.
5) Based on the inspection report and after confirming that manufacturing is taking place as per the specifications and online acknowledgement will be issued by the department.
6) The manufacturers / marketers should furnish the following during inspection of the unit.
   a) Name of the Company & Address of the manufacturing unit and godowns along with name of the person responsible, address, contact number, E mail address etc
   b) GST (VAT/CST) registration no
   c) List of products manufactured with technical and trade name along with samples
   d) Mode of action and methodology of each product manufactured
   e) Type of formulation for each product
   f) Composition of each product
   g) Analytical procedures followed for determination of quality of product
   h) Shelf life of the products
   i) Labels and leaflets of the products
   j) Research data in relation with efficacy of the product. If there is no research data, necessary arrangements should be made immediately for data generation
   k) Source of the raw material (Purchase bills / delivery challan copies, stock register should be furnished as a proof)
   l) Hon'ble court order, if any, with no. & Date:-
   m) Photographs of the premises, machinery and lab equipment.
   n) Affidavit by the manufacturer and chemist on non judicial stamp paper for non violation of Hon'ble High Court order and not to produce products laced with chemicals which will be harmful to humans, plants and environment.
7) After receipt of the acknowledgement, the manufacturers / marketers / dealers should maintain separate stock register for bio-products.
8) Way bills, Invoices, delivery challans should be maintained.
9) Monthly stock report should be furnished to the Department.

Annexure I

Minimum infrastructure to be created by the manufacturers of BIO-PRODUCTS

1. **The minimum infrastructure with respect to manpower shall be as under**

Sr. No.	Manpower	For formulation / manufacturing unit
1	Production Manager	R
2	Quality Control Chemist	R
3	Instrument and process control personnel	R*/NR
4	Maintenance Personnel (Plant and utilities)	R
5	Supervisor	#
6	Store Keeper (Raw material and finished products)	#
7.	Security personnel	#

R = Required
NR = Not Required
* in case of automatic plant
based on firm's requirement

2. Minimum infrastructure with respect to machinery & equipment

S. No.	Equipment	Solid, DP, WG, SP,	WG/G	Liquid (EC, EW, SL)
1.	Feeding channel / Chute	R	R	R
2.	Jaw Crusher (Optional)	R	R	NR
3.	Raw material feed tank	R	R	R
4.	Pulveriser	R	R	NR
5.	Blender	R	R	R
6.	Siever	R	R	R
7.	Homogenizer	R	R	R
8.	Weighing machine / platform balance	R	R	R
9.	Vessel with stirrer	R	R	R
10.	Drier (Optional)	R	R	NR
11.	Cooling machine (Optional)	NR	R	R
12.	Sprayer (Optional)	NR	R	NR
13.	Water tank for liquid	NR	NR	R
14.	Filter	NR	NR	R

DP: Dustable Powder
WG: Water dispersible Granules
SP: Soluble Powder
SL: Soluble Concentrate
G: Granules
EC: Emulsifible Concentrate
EW: Emulsion, oil in Water

3. In case of manufacture of Microbial formulations, the manufacturing unit should contain additional equipment in addition to the equipment mentioned at minimum infrastructure required at S.No:2

a) Boilers, reactors , fermentors
b) Autoclave
c) Centrifuge
d) Soxhlet apparatus
e) Electric oven with thermometer
f) Measuring cylinders and cans
g) Air tight containers
h) Incubators

Note: The laboratory equipment should also contain Microscopes, TLC apparatus, Micro syringes in addition to the equipment mentioned for normal quality control laboratory.

4. Equipment for quality control laboratory

a) Analytical weighing balance
b) Hot air oven
c) Refrigerator
d) pH meter
e) Spectro-photometer / colorimeter (depending on requirement)
f) HPLC (depending on the products analytical process as in the specification)
g) Standard glassware, chemical and general requirements for laboratory
h) Sieve shaker
i) Fume Hood
j) Distilled water still
k) Melting point apparatus
l) GLC (depending upon requirement)
m) Any other specific requirements

5. **Packaging plant and equipment**

a) Packaging machinery.

b) Filling machine (automatic / semi automatic).

c) Weighing machine

d) Bagging machine

e) Sealing machine

f) Labeling equipment. (Optional)

6. **General requirement**

a) Extraction and production room

b) Formulation unit

c) Packing and storage room

d) Quality Control Laboratory

e) Protective clothing

f) Respiratory devices

g) First aid measures

h) Waste disposal arrangement in compliance with Pollution control Board norms

7. **Analysis of bio-products:**

If any product found to be detected with chemicals / impurities etc during analysis at State Laboratories / Central laboratories, the necessary legal action will be initiated. The permissible limits as per the advice of Technical Committee are fixed as follows.

a) FOR PRESENCE OF CHEMICAL SUBSTANCES IN BIO-PRODUCTS:

The limit of Quantification (LOQ) should be **≤0.01%** for all kinds of pesticides / other chemicals which are in Schedule of Insecticide Act, 1968 in Bio Products, and if any bio-product is detected with pesticide **>0.01%** shall be treated as **spurious.**

b) FOR CONTENT ANALYSIS IN BIO-PRODUCTS:

Any deviation in content / quantities described in the label within the range of ± 2.00% will be treated as passed, and deviation beyond ± 2.00% shall be treated as **Misbranded**

8. **Label requirements:**

The following particulars shall be either printed on the label of the innermost container of any bio-product and on the outer most covering in which the container is packed:

a) Name of the manufacturer

b) Name of the marketer, if any.

c) Name of the bio-product (brand name or trade mark under which the bio-product is sold).

d) Kind and name of active and other ingredients and percentage of each in common name accepted by trading community and research organizations for each of the ingredients shall be given.

e) Net content of volume. (The net contents shall be exclusive of wrapper or other material. The correct statement of the net content to terms of weight, measure, number of units of activity, as the case may be, shall be given. The weight and volume shall be expressed in the metric system).

f) Batch number and date of manufacturing.

g) Expiry date, i.e. up to the date the bio-product shall retain its efficiency and safety.

h) The label shall be so affixed to the containers that it cannot be ordinarily removed.

i) The label and leaflets to be affixed or attached to the package containing bio-products shall be printed in English and Telugu language.

j) Maximum Retail Price of the product

9. Field trials for efficacy of the bio-products:

The manufacturers / marketers of bio-products should furnish each bio-product with technical details for organizing paid up trials by scientists at State or Central Research Institutes to study the efficacy of the product.

10. Action on spurious, misbranded bio-products:

a) If any bio product is found laced with pesticides / chemicals, action will be taken as per the existing laws and statutes.

b) If any bio-product is imitation of any other brand / label, action will be initiated as per the existing laws.

c) If a bio-product is not according to specifications as per the composition, legal action shall be initiated as per existing laws.

Annexure II

Protocols required for establishing bio-product manufacturing unit:

The following requirements should be fulfilled:

1. Registration certificate.
    a) In case of companies Registration certificate issued by Registrar of companies along with board resolution copy to be furnished
    b) In case of Partnership firm Partnership deed copy along with VAT registration and PAN card copies of partners should be produced
    c) In case of Proprietorship firm a non judicial affidavit along with VAT registration and PAN card copy of proprietor should be furnished.

2. Statement of production capacity with documentary evidence (as per Industrial Development and Regulation Act).
3. Affidavit from person responsible for quality of finished product.
4. Consent from Pollution Control Board towards safety of environment.
5. Registration with factory inspector of the area regarding labour laws.
6. Provision for safety policy
7. Provision for storage, handling and transportation of raw materials
8. Provision for storage, handling and transportation of finished goods
9. Provision for packaging and labelling
10. Provision for plant, machinery and equipment to be used for manufacture of technical bio-products and formulated product.
11. Provision of skilled manpower.

B. RAJSEKHAR,
Special Chief Secretary to Government (AGRI) (FAC).

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